

## § 316.34

(c) If a sponsor's marketing application for a drug product is determined not to be approvable because approval is barred under section 527 of the Federal Food, Drug, and Cosmetic Act until the expiration of the period of exclusive marketing of another drug, FDA will so notify the sponsor in writing.

[57 FR 62085, Dec. 29, 1992, as amended at 78 FR 35134, June 12, 2013]

### § 316.34 FDA recognition of exclusive approval.

(a) FDA will send the sponsor (or, the permanent-resident agent, if applicable) timely written notice recognizing exclusive approval once the marketing application for a designated orphan-drug product has been approved, if the same drug has not already been approved for the same use or indication. The written notice will inform the sponsor of the requirements for maintaining orphan-drug exclusive approval for the full 7-year term of exclusive approval.

(b) When a marketing application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for a designated orphan drug that qualifies for exclusive approval, FDA will publish in its publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations" information identifying the sponsor, the drug, and the date of termination of the orphan-drug exclusive approval. A subscription to this publication and its monthly cumulative supplements is available from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, and is also available online at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

(c) If a drug is otherwise the same drug as a previously approved drug for the same use or indication, FDA will not recognize orphan-drug exclusive approval if the sponsor fails to demonstrate upon approval that the drug is clinically superior to the previously approved drug.

[78 FR 35135, June 12, 2013]

## 21 CFR Ch. I (4–1–14 Edition)

### § 316.36 Insufficient quantities of orphan drugs.

(a) Under section 527 of the act, whenever the Director has reason to believe that the holder of exclusive approval cannot assure the availability of sufficient quantities of an orphan drug to meet the needs of patients with the disease or condition for which the drug was designated, the Director will so notify the holder of this possible insufficiency and will offer the holder one of the following options, which must be exercised by a time that the Director specifies:

(1) Provide the Director in writing, or orally, or both, at the Director's discretion, views and data as to how the holder can assure the availability of sufficient quantities of the orphan drug within a reasonable time to meet the needs of patients with the disease or condition for which the drug was designated; or

(2) Provide the Director in writing the holder's consent for the approval of other marketing applications for the same drug before the expiration of the 7-year period of exclusive approval.

(b) If, within the time that the Director specifies, the holder fails to consent to the approval of other marketing applications and if the Director finds that the holder has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated, the Director will issue a written order withdrawing the drug product's exclusive approval. This order will embody the Director's findings and conclusions and will constitute final agency action. An order withdrawing the sponsor's exclusive marketing rights may issue whether or not there are other sponsors that can assure the availability of alternative sources of supply. Once withdrawn under this section, exclusive approval may not be reinstated for that drug.